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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,703	08/21/2000	Warren Hoeffler	XGEN-110-USA	8907

7590 12/05/2001

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EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 12/05/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/622,703	Hoeffler
Examiner	**Art Unit**
Arun Chakrabarti	1655

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address** --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Apr 6, 2001 .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-14 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/622,703 .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CAR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14, drawn to method of detecting transcription activity by detecting the presence or absence of a nick in the DNA molecule.

Group II, claims 15-20, drawn to method of screening for an active transcription factor.

Group III, claim(s) 21-31, drawn to method of modulating the transcription.

Group IV claim(s) 32-42, drawn to kits containing DNA molecule.

Group V, claim(s) 43-47, drawn to method of detecting consensus sequence by hybridization.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: A preliminary search on claim 1 revealed an anticipatory 102 (b) reference (Gansz et al., Molecular and General Genetics, (1991), Vol. 225,

pages 427-434) which clearly indicates that claims listed as Groups I-V lack the same or corresponding special technical features.

3. During a telephone conversation with Michael Ward, on April 25, 2001, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-14. Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-47 are withdrawn from further consideration by the examiner, 37 CAR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> > (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 4-8 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Gansz et al. (Molecular and General Genetics, (1991), Vol. 225, pages 427-434).

Gansz et al teach a method of detecting transcription activity (Summary) comprising the steps of :

a) providing a DNA template comprising at least one binding region for a transcription factor (Page 428, column 1, Materials and Methods Section, DNA isolation subsection);

b) contacting the DNA template with at least one transcription factor (Figures 1 and 2 and Materials and Methods Section, Gel-retardation assay subsection);

c) detecting the presence or absence of a nick in the DNA template, wherein the presence of a nick in the DNA template indicates transcription activity (Summary, lines 11-12 and Results and Discussion section, The DsbA protein induces DNA nicking subsection and Figures 2-5).

Gansz et al teach a method wherein the presence or absence of a nick in a DNA molecule is measured by determining the change in electrophoretic mobility of nicked DNA on an electrophoretic gel by a DNA sequencing assay (Figure 5 and Materials and Methods Section, DNAse I foot printing subsection).

Gansz et al teach a method wherein the presence or absence of a nick in a DNA molecule is determined by a primer extension, polymerase chain reaction and amplification reaction (Materials and Methods Section, DNA sequencing subsection).

Gansz et al teach a method wherein the presence or absence of a nick in a DNA molecule is determined by a protein binding assay (Figure 2 and Results and Discussion section, Gel Retardation Assay subsection).

Gansz et al teach a method wherein the DNA is affixed to a gel matrix (Figures 2-5 and Materials and Methods Section, In vitro transcription assays subsection).

Gansz et al teach a method wherein the transcription factor is in a nuclear cell extract (Materials and Methods Section, Enzyme and Protein isolation subsection).

Gansz et al teach a method wherein the DNA template is inserted into a viral vector and introduced into a cell (Figure 1 and Results and Discussion section, Cloning of gene dsbA subsection and over-expression of gene product DsbA subsection).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-2 and 4-14 are rejected under 35 U.S.C. 103 (a) over Gansz et al. (Molecular and General Genetics, (1991), Vol. 225, pages 427-434) in view of Mirzabekov et al. (U.S. Patent 5,851,772) (December 22, 1998).

Gansz et al teach the method of claims 1-2, 4-8 and 10-13 as described above.

Gansz et al do not teach the method wherein the DNA is affixed to a biological chip.

Mirzabekov et al teach the method wherein the DNA is affixed to a biological chip. (Figures 1 and 3 and Column 2, lines 42-56).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the DNA affixed to a biological chip of Mirzabekov et al. in the method of detecting transcription activity of a DNA molecule of Gansz et al., since Mirzabekov et al. state, "Still another object of the present invention to provide an

easy method for identifying and subsequently enriching specific sequences of DNA. A feature of the present invention is the ease of use of a large number of oligomers immobilized on a fractionation chip and which are complementary to the desired DNA sequences, to isolate the target sequences contained on ssDNA. An advantage of the invented method is the dramatic reduction in the required number of immobilized oligomers to pinpoint desired DNA sequences compared to typical SHOM sequencing techniques. (Column 2, lines 43-53)." An ordinary practitioner would have been motivated to combine and substitute the DNA affixed to a biological chip of Mirzabekov et al. in the method of detecting transcription activity of a DNA molecule of Gansz et al., in order to improve the transcription activity detection of a large number of DNA molecules in a short period of time and also in order to achieve the express advantages, as noted by Mirzabekov et al, of an invention which provide an easy method for identifying and subsequently enriching specific sequences of DNA and also to exploit the ease of use of a large number of oligomers immobilized on a fractionation chip which are complementary to the desired DNA sequences, to isolate the target sequences contained on ssDNA and also to achieve the advantage of a method which provides the dramatic reduction in the required number of immobilized oligomers to pinpoint desired DNA sequences compared to typical SHOM sequencing techniques.

8. Claims 1-8 and 10-13 are rejected under 35 U.S.C. 103 (a) over Gansz et al. (Molecular and General Genetics, (1991), Vol. 225, pages 427-434) in view of Hodgson et al. (U.S. Patent 5,854,020) (December 29, 1998).

Gansz et al teach the method of claims 1-2, 4-8 and 10-13 as described above.

Gansz et al do not teach the method wherein the transcription initiation site is determined by S1 nuclease assay.

Hodgson et al teach the method wherein the transcription initiation site is determined by S1 nuclease assay (Column 5, lines 21-25).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the transcription initiation site determination by S1 nuclease assay of Hodgson et al. in the method of detecting transcription activity of a DNA molecule of Gansz et al., since Hodgson et al. state, "Within the promoter sequence will be found a transcription initiation site conveniently defined by mapping with nuclease S. (Column 5, lines 22-24)." An ordinary practitioner would have been motivated to combine and substitute the transcription initiation site determination by S1 nuclease assay of Hodgson et al. in the method of detecting transcription activity of a DNA molecule of Gansz et al., in order to improve the transcription activity detection and also in order to achieve the express advantages, as noted by Hodgson et al, of mapping with nuclease S1 which conveniently define transcription initiation site.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W.Gary Jones, can be reached on (703)308-1152.

Any inquiry of general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Arun Kr. Chakrabarti

Arun Chakrabarti,

Patent Examiner

Art Unit 1655

December 4, 2001